TONY WEST
Assistant Attorney General

JOSEPH P. RUSSONIELLO (CA Bar No. 44332)
United States Attorney
JOANN M. SWANSON (CA Bar No. 88143)
Chief, Civil Division
SARA WINSLOW (DC Bar No. 457643)
JULIE A. ARBUCKLE (CA Bar No. 193425)
Assistant United States Attorneys
450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
Telephone: (415) 436-6925 (Winslow)
(415) 436-7102 (Arbuckle)
Facsimile: (415) 436-6748
sara.winslow@usdoj.gov
julie.arbuckle@usdoj.gov

JOYCE R. BRANDA
PATRICIA R. DAVIS
RENÉE S. ORLEANS
Attorneys
Civil Division
United States Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 514-4504
Facsimile: (202) 305-4117
renee.orleans@usdoj.gov

Attorneys for the United States of America

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES *ex rel.* STROM, Plaintiffs, v. SCIOS, INC. and JOHNSON & JOHNSON, Defendants.	No. C 05-3004 CRB **UNITED STATES' COMPLAINT** **JURY TRIAL DEMANDED**

1. The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of Defendants, Scios, Inc. ("Scios") and Johnson & Johnson ("J&J"). Scios and J&J illegally marketed and promoted the cardiac drug Natrecor for serial, scheduled outpatient infusions — a use not approved by the Food and Drug Administration ("FDA") and not covered by the federal health care programs — causing false claims to be submitted.

I. NATURE OF ACTION

2. The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33 (2008), and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

3. The United States bases its claims on Defendants causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1) (2008).

4. Within the time frames detailed below, Scios and J&J engaged in a fraudulent scheme to market and promote Natrecor for serial, scheduled outpatient infusions — a use not approved by the FDA. Such an unapproved use is also known as an "off-label" use because it is not included in the drug's FDA-approved product label. Scios's marketing strategy for Natrecor included generating an outpatient market for the drug by marketing it for serial, scheduled infusions. Scios's extensive outpatient marketing campaign was clearly directed at an off-label use of Natrecor.

5. Generally, no payments may be made under Medicare for expenses incurred for items and services, including drugs, that are not "reasonable and necessary" for the diagnosis and treatment of an illness. Medicare does not cover off-label uses unless determined to be "medically accepted." The scheduled, serial outpatient infusions were neither reasonable and necessary nor medically accepted. Indeed, the off-label use was unsupported by *any* credible

study showing that the serial outpatient infusions had any benefit for patients. In June 2005, a blue-ribbon panel headed by a top cardiologist chosen by Scios found that "because sufficient evidence is not currently available to demonstrate benefit" Natrecor "should not be used "[f]or intermittent outpatient infusion" or "[f]or scheduled repetitive use." Through its pervasive off-label marketing scheme, Scios falsely and fraudulently caused the federal health care programs – in particular, Medicare – to pay substantial amounts for this off-label use of Natrecor.

II. JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and1345.

7. This Court may exercise personal jurisdiction over Scios and J&J pursuant to 31 U.S.C. § 3732(a), because Scios is located in the Northern District of California, and because Scios and J&J transact business in the Northern District of California. In particular, J&J conducts business throughout California, including in the Northern District of California, and also conducts business in this District and elsewhere in California through its wholly owned subsidiary, Scios. Additionally, both before and after it acquired Scios, J&J officers and employees came to the Northern District of California on a regular basis to meet with, oversee, and direct Scios's activities as more fully described below.

8. Venue is proper in the Northern District of California under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Scios and J&J have transacted business in this District and have committed acts proscribed by 31 U.S.C. § 3729 in this District.

III. PARTIES

9. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicare program; the Department of Defense's TRICARE Management Activity ("TRICARE"); and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program

("FEHBP") (collectively, "federal health care programs").

10. Relator Joe Strom is a resident of Utah and was formerly employed by Scios as an Area Manager from approximately October 2003 until September 2004. In July 2005, Mr. Strom filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1) (2008).

11. Defendant Scios is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of Delaware, with its principal places of business being located in Alameda County and Santa Clara County, California. Scios is a wholly owned subsidiary of J&J. Since August 13, 2001, and at all times relevant to the complaint, Scios has been marketing and selling Natrecor, a cardiovascular drug.

12. Defendant J&J is, and at all times since April 29, 2003 was, the parent company of Scios. J&J is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. J&J manufactures, markets, and sells a wide range of pharmaceutical, medical, and related products. J&J is qualified to do business in California and is doing business in California.

13. There exists, and at all times since April 29, 2003 existed, a unity of interest and ownership between Defendants Scios and J&J such that any individuality and separateness between them have ceased, and Scios is the alter ego of J&J in that J&J has been controlling the business and daily operations of Scios.

14. Specifically, J&J has been exercising strict supervision, control, and dominion over Scios's activities, decisions, policies, and practices related to sales goals, sales tactics, compliance, regulatory affairs, medical affairs, research and development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations. J&J set Scios's business objectives and sales goals and regularly reviewed and approved Scios's sales numbers and projections. In February 2004, Scios confirmed to J&J that its strategies included achieving the 2004 Business Plan, growing

Natrecor's revenue to $1 billion by 2007, developing relationships with assigned J&J resources, effectively partnering with J&J affiliates, adopting the best aspects of J&J culture, and implementing J&J's performance review system and compensation programs.

15. By way of further example, J&J decided to redeploy sales representatives from another subsidiary, Centocor, to Scios, to realign Scios's sales force, and to transfer the manufacturing of Natrecor to J&J's central pharmaceutical manufacturing facility, Global Biologics Supply Chain. J&J also identified critical employees to retain with the incentive of retention bonuses approved by J&J, set Scios's aggregate headcount targets, and imposed hiring constraints on Scios. In January 2006, J&J executives decided to reduce Scios's sales force, to have them co-promote with another J&J subsidiary, Ortho-Biotech, and to relocate Scios's headquarters to a site in Mountain View, California occupied by another J&J subsidiary, Alza. In effect, J&J operated its subsidiaries as divisions of the same company.

16. Since the April 2003 acquisition, J&J has been Scios's sole owner. After the acquisition, Scios ceased filing reports with the SEC and J&J began including Scios's revenue as part of J&J's revenue in J&J's SEC filings. J&J and Scios also have shared directors and in-house counsel. Scios's President and Chief Executive Officer ("CEO") has been directly reporting to a J&J Company Group Chairman, who in turn reports to J&J's Executive Committee and Board of Directors. In February 2004, J&J replaced Scios's President and CEO, Richard Brewer, with a J&J executive, Jim Mitchell, and determined the amount of compensation, bonuses, and stock options Jim Mitchell would receive. Other members of Scios's Corporate Management Committee have been reporting directly to either to J&J or to Scios's President and CEO, who in turn, reports directly to J&J. J&J gave some members of Scios's Corporate Management Committee official J&J job titles and responsibilities for activities at J&J subsidiaries other than Scios. J&J also set the compensation and bonuses for Scios executives. Thus, Scios's executives, officers, directors, and counsel have not been acting independently in the interest of Scios, but were supervised and controlled by J&J.

17. Adherence to the fiction of the separate existence of Scios as an entity distinct from J&J would permit an abuse of the corporate privilege and would sanction fraud and promote injustice. Although Scios continues to exist as a corporate entity, it is in the process of closing and has limited assets. The United States is informed and believes that since J&J acquired Scios for approximately $2.4 billion in April 2003, J&J has been controlling Scios's budget, has had to approve all significant spending at Scios, has allotted specific amounts for Scios to spend, and has set aside funds to cover Scios's expenses when Scios's final year end sales number was less than expected. The United States is further informed and believes that Scios's ability to pay its liabilities is dependent upon J&J, and that J&J has authorized depletion of Scios's assets to the extent that Scios has insufficient funds to pay the monetary damages and penalties the United States identifies below.

IV. THE FALSE CLAIMS ACT

18. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1) (2008).

The FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
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> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729 (2008).

19. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 per false claim for violations occurring on or after September 29, 1999.

V. THE FEDERAL HEALTH CARE PROGRAMS

A. The Medicare Program

(1) Medicare Parts A and B

20. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426-426a, 1395o.

21. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts. Part A authorizes payment for institutional care, including hospital, skilled nursing facility, and home health care. 42 U.S.C. §§ 1395c–1395i. Part B ("Supplementary Medical Insurance for the Aged and Disabled") generally covers, *inter alia*, drugs which are provided incident to a physician's service and cannot usually be self-administered (such as Natrecor). 42 U.S.C. § 1395k; 42 C.F.R. §§ 410.26, 414.701, 410.10.

22. Under the Medicare program, CMS makes payments retrospectively (after the services are rendered) to providers for inpatient and outpatient services.

23. Generally, Medicare's hospital outpatient prospective payment system ("OPPS") reimburses covered outpatient services furnished by hospitals participating in the Medicare program (with some exceptions). 42 U.S.C. § 1395l(t); 42 C.F.R. § 419.20. Under the OPPS, hospitals are paid a set amount of money to provide certain outpatient services to Medicare beneficiaries.

24. Medicare also allows additional payments for, *inter alia*, a new medical device,

drug, or biological through the transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals. 42 U.S.C. § 1395l(t)(6); §§ 419.20-21. A new drug or biological may qualify for certain additional payments in the hospital outpatient setting if (1) it was not being made as of December 31, 1996, and (2) the cost of the drug or biological is not insignificant in relation to the particular fee schedule amount. 42 U.S.C. § 1395l(t)(6).

25. For services provided incident to a physician's service under Part B, Medicare will generally pay 80 percent of the "reasonable" charge for medically necessary items and services provided to beneficiaries. 42 U.S.C. §§ 1395l (a)(1), 1395y(a)(1). For most services, the reasonable charge is determined based on criteria that include (a) the provider's customary charge, and (b) the prevailing charge for the service in the locality. 42 C.F.R. §§ 405.501-04.

26. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries." 42 U.S.C. § 1395h. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims and cost reports.

27. CMS also contracts with private insurance carriers to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. The carriers receive, process and pay claims under Part B for drugs from various doctors and other Medicare providers and suppliers.

28. Since approximately November 2006, and thereafter, Medicare administrative contractors ("MACs") began replacing the carriers and fiscal intermediaries. *See* 71 Fed. Reg. 67960, 68181 (Nov. 24, 2007). Hereinafter "carriers," "fiscal intermediaries," and "MACs" will be referred to collectively as "Medicare Contractors." The Medicare Contractors generally act on behalf of CMS. 42 C.F.R. § 421.5(b).

(2) Off-label Coverage under Medicare

29. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). Drugs approved for marketing by the FDA are considered safe and effective when used for indications specified on the labeling.

30. Medicare coverage of an outpatient drug for an off-label use occurs only where the use is medically accepted, taking into account the major drug compendia, (*e.g.*, Drugdex, American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information), authoritative medical literature, and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual Chap. 6 § 30 & Chap. 15, § 50.4.1. & .2.

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note).

C. The Federal Employee Health Benefits Program

34. The FEHBP is a federally-funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. §§ 8901 *et seq*.

35. The Office of Personnel Management ("OPM") administers this program and contracts with various health insurance carriers to provide services to FEHBP members. *Id.* at §§ 8902, 8909(a).

36. Monies for the FEHBP are maintained in the Employees Benefits Fund ("Treasury Fund"), which OPM administers. *Id.* at § 8909(a).

37. The Treasury Fund — which the United States Treasury holds and invests — is the source of all relevant payments to the insurance carriers for services rendered to members. *Id*. § 8909.

38. Benefits under the FEHBP program are payable only when medically necessary to prevent, diagnose, or treat an illness, disease, injury or condition. During the relevant time period, the benefit plans for FEHBP insurance carriers Blue Cross and Blue Shield, Government Employees Hospital Association, Inc., and Mail Handlers Benefit Plan specifically provided that they did not cover services, drugs, or supplies that are not medically necessary.

VI. FACTUAL ALLEGATIONS

A. FDA Approval of Natrecor

39. Scios developed the drug Natrecor (generic name is nesiritide) in the 1990s for the short-term treatment of patients with acutely decompensated congestive heart failure ("ADHF"). Decompensation means that the patient's lungs have accumulated fluid.

40. Scios initially sought FDA approval of Natrecor to treat ADHF in 1998, but the FDA rejected the application due to safety concerns, particularly relating to the drug's propensity to cause symptomatic hypotension (unusually low blood pressure).

41. Scios subsequently sponsored an additional study called VMAC (**V**asodilation in the **M**anagement of **A**cute **C**ongestive Heart Failure) to determine dosages of Natrecor that effectively treated ADHF but were less likely to cause hypotension.

42. The patients in VMAC were hospitalized with ADHF with dyspnea (shortness of breath) at rest and received Natrecor infusions for an average of 36 hours, ranging from 24 to 48 hours. The study compared the effect of Natrecor, placebo, and IV nitroglycerin when added to background therapy (IV and oral diuretics, non-IV cardiac medications, dobutamine and dopamine). The primary endpoints of the study were the change from baseline in pulmonary capillary wedge pressure ("PCWP") (a measure of the pulmonary vascular pressure of the heart, reflecting its workload) and the change from baseline in patients' dyspnea after three hours.

43. In August 2001, based on the VMAC study and results, the FDA approved Natrecor for a limited use. The Indications and Usage section of the FDA-approved label specifies the approved indication:

> Natrecor (nesiritide) is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. In this population, the use of Natrecor reduced pulmonary capillary wedge pressure and improved dyspnea.

44. The label states that VMAC included patients "who required hospitalization for management of shortness of breath at rest due to acutely decompensated CHF." In the Precautions section, the label states that "Natrecor should be administered only in settings where blood pressure can be monitored closely" in order to determine whether a patient is developing hypotension.

B. CMS Coding

45. Scios submitted an application to CMS for an Ambulatory Payment Classification ("APC") pass-through code under OPPS for Natrecor. CMS issued an APC pass-through code under OPPS for Natrecor, effective April 1, 2002.

46. Scios submitted an application to CMS for a J code for Natrecor for services rendered in the outpatient setting. A J code is used for Medicare billing to report injectable drugs that ordinarily cannot be self-administered. CMS issued a J code for Natrecor for services rendered in the outpatient setting, effective January 1, 2003.

47. Billing under these codes is proper only if the services are covered under Medicare as medically necessary.

C. The FUSION Outpatient Studies

(1) FUSION I

48. Immediately after the launch of Natrecor in August 2001, Scios started the FUSION I trial (derived from the study's fully name — Management of Heart Failure after Hospitalization with **F**ollow **U**p **S**erial **I**nfusions of **N**esiritide in an Outpatient Setting). FUSION I was a pilot study designed only to assess the ability of a patient with chronic congestive heart failure to tolerate these serial infusions (*i.e.,* to study the safety of serial infusions) and thus was not a study that could be used to determine the efficacy of the serial

infusions.

49. Scios described the study as a multi-center (46 sites), randomized, three-treatment arm, open-label (thus the doctors and patients knew who were receiving Natrecor) pilot study of 210 chronic heart failure patients at high risk for rehospitilization.

50. The patients generally had weekly outpatient visits for 12 weeks and the patients receiving Natrecor got a four to six hour infusion at each weekly visit.

51. Scios announced the results of FUSION I in September 2003, stating that the study suggested that weekly outpatient infusions of Natrecor could be safely administered to treat high-risk patients with advanced CHF. While the study was not designed to support any conclusion about the efficacy of Natrecor for serial infusions, a Scios press release nevertheless announced that "[d]ata from the FUSION I study suggests that the Natrecor-treated patients show improvements in clinical status with longer life expectancy and a lower frequency of hospitalizations compared to the group of patients receiving standard care."

52. Scios disseminated the results of FUSION I widely, claiming that it supported not only the safety but the efficacy of Natrecor for serial infusions.

(2) FUSION II

53. In 2004, Scios, now part of J&J, started a second trial on the outpatient use of Natrecor. Unlike FUSION I, FUSION II was a blinded and controlled study. It was also specifically designed to determine the efficacy of serial outpatient Natrecor infusions and to measure whether these infusions lowered mortality and hospitalization rates.

54. In 2007, Scios released the results of its FUSION II trial. The study did not show any significant benefits of serial outpatient Natrecor infusions in comparison to standard care.

D. <u>Defendants' Knowledge Of The Off-Label Nature of Outpatient Infusions</u>

55. Defendants knew that Natrecor was approved only for patients with ADHF who have dyspnea at rest or with minimal activity. Nevertheless, Defendants marketed Natrecor for use in patients who had congestive heart failure ("CHF"), but were not acutely decompensated

and/or did not have dyspnea at rest or with minimal activity.

56. Specifically, Defendants marketed Natrecor for use in chronic CHF patients in outpatient settings on a scheduled basis.

57. By definition, an acute episode of decompensated CHF with dyspnea at rest or with minimal activity is an emergency situation that does not occur on a scheduled basis. Defendants understood this definition. For example, in its June 2001 Prospectus Supplement for its common stock offering, Scios explained that "[m]any CHF patients will eventually experience a rapid deterioration, or decompensation, and require urgent treatment in the hospital. This condition is called acute CHF."

58. Defendants knew that outpatient infusions would generally not be for the acutely decompensated patients described in Natrecor's label, except in the rare circumstance when an acutely decompensated patient with dyspnea at rest or with minimal activity sought care from a doctor's office or clinic instead of a hospital or emergency room. For example, on April 9, 2001, Scios Director of Operations Rosemary Malvey characterized Natrecor as "strictly a hospital product." In early 2002, Scios hired a consultant (Adair Greene) to draft a "Natrecor Out-patient Infusion Business Plan." That document stated, *inter alia*: "Because patients being treated in an outpatient setting will be in a relatively compensated state, the appropriate dose of Natrecor infusion may be lower than the dose used in acutely decompensated patients"; and "There is an unmet need for effective outpatient treatment of advanced chronic CHF." In addition, the dosage used for the outpatient infusions of Natrecor was at odds with the dosage used for the acute patients in VMAC, the study upon which Natrecor's FDA approval was based. VMAC involved hospitalized patients who received Natrecor infusions ranging from 24 to 48 hours, while the outpatient infusions typically lasted six hours or less.

59. During 2002, Scios convened an Outpatient Infusion Advisory board to, *inter alia*, advise Scios on designing a clinical trial that would lead to FDA approval of an outpatient indication for Natrecor. Defendants, however, never applied for FDA approval of a new

Natrecor indication for outpatient CHF management, and Defendants continued to sell Natrecor in a 1.5 mg vial, which was designed for an approximately 24-hour infusion, in contrast to the much smaller amount that was typically used for an outpatient infusion.

60. Nevertheless, at Scios's April 2003 National Sales Meeting, Scios Manager of Outpatient Marketing Russell Cox discussed the outpatient market for Natrecor and noted that chronic patients were worth a great deal of money. At Scios's October 2003 National Sales Meeting, Cox noted that half of the Natrecor business was coming from the outpatient segment, and that Natrecor would ultimately go from an acute medication to a chronic medication. He further noted that the outpatient serial dose of Natrecor used for FUSION I was not within the label.

61. Defendants knew that scheduled outpatient infusions of Natrecor were outside of the FDA-approved label indication. For example, at Scios's April 2002 National Sales Meeting, Scios Marketing Director George Mahaffey stated that intermittent infusions were not on label, and characterized the FUSION study as off label. In a February 10, 2003 public conference call by Scios and J&J regarding their acquisition agreement, George Schreiner, Scios's Vice President and Chief Scientific Officer, said that the outpatient use of Natrecor which was being studied in the FUSION I trial "of course is not currently within label but we are conducting the appropriate studies to potentially make it eligible for a label extension."

E. Defendants' Scheme To Market Natrecor For Serial Outpatient Infusions

(1) Defendants' Focus On The Outpatient Market

62. At Scios's April 2002 National Sales Meeting, Scios Marketing Director George Mahaffey discussed the market for outpatient infusions with the sales force, including, *inter alia*, converting outpatient clinics from a class of infusion cardiac drugs known as inotropes to Natrecor. Infusions of inotropes were generally used in the outpatient setting for chronic CHF patients. Scios wanted these clinics to use Natrecor in a similar manner. Mahaffey referred to hospital-based infusion clinics and heart failure clinics as banks, and physician office clinics as

ATMs.

63. A draft of the Natrecor 2003 Business Plan (reviewed by Scios CEO Richard Brewer) listed as one of Scios's 2003 objectives: "Achieve 2% penetration of the patients treated serially via outpatient infusion for CHF by year-end 2003," and as one of its long-term objectives: "Develop the outpatient infusion market and achieve at least 15% penetration of the estimated 145k patients treated with serial outpatient infusion by 2007." Scios estimated Natrecor's 2002 outpatient penetration rate to be 1% of available patients.

64. In 2003, Defendants estimated that the size of the outpatient market was approximately 125,000 patients and that the average revenue that could be generated per person from outpatient use of Natrecor was $9,600, as compared to $1,000 in the inpatient setting. In approximately late 2002 or early 2003, a presentation at a Scios sales management meeting in Dallas discussed the potential for patients receiving 12 vials every three months in an outpatient setting (*i.e.*, approximately one vial per week). A presentation at Scios's April 2003 National Sales Meeting stated that the 2003 Natrecor outpatient revenue represented 2,060 patients at 24 vials per patient.

65. On June 6, 2002, Kim Hillis, Scios's Director of Sales, wrote to the sales management with her thoughts on the areas where Scios's marketing, clinical, and sales efforts should be directed to achieve $1 billion in annual sales of Natrecor. Outpatient infusion was the first area Hillis listed. At Scios's April 2003 national sales meeting, Russell Cox, Scios's Manager of Outpatient Marketing, told the sales force that outpatient infusion "represents our largest growth opportunity for Natrecor." In January 2005, Defendants estimated that Natrecor outpatient sales had increased by 173% for 2004, would increase by 81% for 2005, and that their outpatient infusion business would grow at a higher rate than their base hospital business.

66. Defendants maintained an Outpatient Infusion Center database from March 2003 to July 2004 to, *inter alia*, evaluate the market opportunity represented by outpatient infusion centers and measure the amount of revenue being generated by outpatient infusion centers as

related to their use of Natrecor. One of the aims of the database was to accelerate adoption of Natrecor in the outpatient infusion market.

67. In addition to the control J&J has been exercising over Scios, J&J was directly involved in Scios's marketing of Natrecor for serial, outpatient use. J&J knew and approved of Scios's marketing goals and strategies that included marketing Natrecor for serial, outpatient use. For example, even before the acquisition, J&J officers learned during the due diligence process that:

a. The FDA had only approved Natrecor for treatment of acute congestive heart failure, not treatment of chronic congestive heart failure;

b. Despite Natrecor's approved use, Scios was marketing Natrecor for serial outpatient use;

c. There would be significant upside potential if Scios were able to achieve an indication for chronic outpatient use – *i.e.*, the sales forecast would increase by $330 million (from $600 million to $930 million);

d. Scios's Business Plan included continuing to market Natrecor for outpatient use;

e. Success in the outpatient setting would depend on Medicare continuing to reimburse for "treatment on a chronic basis," and that until Medicare's view was clear, "it is a risk that is difficult to assess;" and

f. Scios was facilitating Medicare reimbursement for outpatient use through its Natrecor Reimbursement Quick Reference guide, its reimbursement support hotline, and its website, which also indicated that there was a financial incentive for physicians to use Natrecor in the outpatient setting.

68. Just after the acquisition, J&J and Scios jointly presented their plan to grow the outpatient congestive heart failure market to $100 million in 2004, $200 million in 2005, over $300 million in 2006, and over $400 million in 2007. This plan was a key component of J&J's plan to grow Scios's total revenue to over $1 billion by 2007.

69. Further evidencing J&J's direct involvement in Scios's marketing of Natrecor for serial outpatient use, on June 27, 2003, the Chairman of J&J's Board of Directors, Bill Weldon, visited Scios and reviewed Defendants' 2003/2004 Natrecor Business Plan, which discusses the plan to continue marketing Natrecor for outpatient use and sets separate sales goals for

"Outpatient" sales. Likewise, in March 2004, J&J Company Group Chairman Joe Scodari reviewed and approved the 2004 Business Plan and Strategic Plan. The 2004 Business Plan: (a) discusses the plan to continue marketing Natrecor for outpatient use by "[e]stablish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting (increase monthly infusion revenue from $3M to $9.5M)"; (b) provides separate sales goals for "Acute CHF" sales and "Outpatient" sales, thereby differentiating outpatient infusions from the approved indication; and (c) estimates that there are 129,000 eligible outpatient patients who may use 17 vials of Natrecor each, as opposed to 2.6 vials for each eligible "Acute CHF" patient. The 2004 Strategic plan likewise discusses: (a) Scios's "Development Strategy for Natrecor for the Chronic Intermittent Outpatient Market;" (b) "Leveraging the Natrecor Platform" for Outpatient Chronic CHF; (c) "Improv[ing] infusion procedure payment rate in hospital outpatient department;" and (d) "Increas[ing] business acumen of treating physicians."

70. Defendants used numerous tactics to encourage health care providers to use Natrecor in CHF patients in outpatient clinics on a scheduled basis. Several examples follow.

71. Defendants encouraged health care providers to start outpatient infusion clinics that used Natrecor. For example, Defendants paid grant funds and provided other resources to health care providers to use in starting outpatient infusion clinics. Among other things, Scios provided health care professionals with its Heart Failure Clinic Marketing Resource Kit, which included, *inter alia,* form press releases for outpatient clinics to announce their activities, and other promotional materials. Scios also provided health care professionals with its Clinical Resource Compendium for the Heart Failure Clinic which, *inter alia*, provided contact information for existing outpatient clinics that used Natrecor, as well as for medical supply and equipment companies and reimbursement consultants. In late 2003, Kim Hillis, Scios's Director of Sales, directed sales management to utilize Defendants' Scientific Affairs Managers to help develop new Natrecor outpatient infusion clinics.

72. Defendants' sales force visited existing outpatient infusion clinics that used a class of infusion cardiac drugs called inotropes, in an effort to encourage the clinics to administer Natrecor to their patients instead of inotropes. For example, on December 13, 2002, Director of Sales Hillis directed the sales force to "[t]arget existing outpatient infusion clinics using a high volume of inotropes." A breakout session at Scios's 2003 National Sales meeting trained the sales force to "flip" existing clinics to Natrecor use. Defendants implemented this plan. For example, Defendants got Owensboro Heart and Vascular clinic in Kentucky to transition numerous CHF patients from inotrope therapy to outpatient Natrecor infusions in part by funding this clinic to study the effects and benefits of such transitions. Owensboro Heart and Vascular subsequently submitted claims to Medicare totaling more than $800,000 for serial, outpatient infusions of Natrecor. Defendants also used Owensboro Heart and Vascular's study to encourage other outpatient clinics to convert from inotropes to Natrecor.

73. A draft of the Natrecor 2003 Marketing Plan (reviewed by Scios CEO Brewer) stated that "[t]he sales force is identifying and targeting the 10 top outpatient infusion centers in each area business unit and will focus educational and informational programs on the safe and appropriate use of Natrecor in these centers during 2003."

74. Defendants' management trained the sales force to market for outpatient use because "that's where the money is," and trained the sales force to discuss "symptomatic" patients rather than using the word "acute" when selling Natrecor to the outpatient market. Management directed that one of the Scios sales force's objectives for 2002 was to expand the use of Natrecor in outpatient infusion centers. A January 2003 presentation by Scios Cardiovascular Specialist (sales representative) Luanne Morris entitled Outpatient Infusion Centers trained the Scios sales force to target hospital outpatient clinics and physicians' offices. In approximately late 2002 or early 2003, at a sales management meeting in Dallas, management was told to direct the sales representatives to "[a]ggressively pursue business" in the outpatient infusion market. During a sales representative training session in February 2004, Defendants

discussed separate sales goals for "Acute CHF" sales, and "Outpatient" sales, and their plan to continue marketing Natrecor for outpatient use by "establish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting." They further instructed the sales force that the "Outpatient Market Development Strategy" was to maximize exposure to outpatient infusion data such as FUSION I, to increase the number of treaters through Centers of Excellence (discussed below), the ADHERE LM registry (discussed below), and FUSION II, and to maintain or improve the positive reimbursement environment through a reimbursement initiative with J&J.

75. Despite all of Defendants' efforts to market Natrecor for outpatient infusions, Defendants told the FDA in an April 11, 2005 letter that "Scios does not currently market Natercor in a manner that suggests that it should or should not be used specifically in the outpatient setting," and that "Scios's written policies and training materials emphasize the company's unambiguous policy that the promotion of serial or scheduled administration of Natrecor is not permitted."

(2) Defendants' Payments to Health Care Professionals

76. One of Defendants' Centers of Excellence (discussed below) was South Bay Cardiovascular Associates in West Islip, New York ("South Bay"). The Natrecor sales force received training on South Bay's outpatient use of Natrecor, including a presentation during the September 29 to October 3, 2003 sales training, during which the sales force was taught that Natrecor "can be safely and effectively used on an intermittent basis." From 2003 to 2005, Defendants paid over $100,000 to a nurse at South Bay. This nurse made promotional speeches relating to the outpatient use of Natrecor; she trained other health care providers on the outpatient use of Natrecor; and her name appears as author on various publications relating to the outpatient use of Natrecor, including, *inter alia,* "Nesiritide in an Outpatient Infusion Clinic Setting - Case Studies of 17 patients," which was published in the Journal of Cardiac Failure in August 2002.

77. Defendants paid numerous other health care professionals who authored articles,

made promotional speeches, and taught continuing medical education courses that promoted the outpatient use of Natrecor. Several examples follow.

78. From 2003 to 2005, Defendants paid a cardiologist at Hackensack University Medical Center over $250,000. This doctor made speeches promoting the outpatient use of Natrecor, and was listed as author of articles on Natrecor, including at least two that were ghostwritten at Defendants' expense. For example, the doctor is listed as one of many authors in the article, "Safety and Feasibility of Using Serial Infusions of Nesiritide for Heart Failure in an Outpatient Setting (From the FUSION I Trial)."

79. On or about May 2004, defendants paid a $500,000 grant to the University of Texas Southwestern Medical Center for a cardiology fellowship. A cardiologist at the University of Texas Southwestern Medical Center was a key proponent of Natrecor outpatient infusions, authoring articles and giving speeches that promoted the outpatient use of Natrecor. For example, at an Annual Scientific Meeting in Las Vegas in September 2003, this doctor disclosed he was a Scios consultant who had received honoraria, an educational grant, and research support from Scios, and then discussed FUSION I and using Natrecor in the outpatient setting for treating chronic decompensated heart failure patients.

80. From 2003 to 2005, a cardiologist and former Medical Director at the Midwest Heart Specialists received over $160,000 from Scios, for speaking in favor of Natrecor, and the Midwest Heart Foundation, which is affiliated with Midwest Heart Specialists, received over $250,000 in grant funds from Scios.

81. All of these healthcare providers promoted the outpatient use of Natrecor for serial infusions despite the lack of any scientific evidence to support the efficacy of such treatment.

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(3) Defendants' Centers of Excellence Program

82. Defendants also encouraged scheduled outpatient infusions of Natrecor through their Centers of Excellence (later renamed Commitment to Excellence) Program. Under this program, Defendants sent health care practitioners who were potentially interested in starting outpatient infusion clinics to existing outpatient clinics that used Natrecor, in order to observe and learn. For example, prior to opening their own outpatient clinics, doctors and nurses from New York and Rhode Island visited South Bay to meet with the South Bay nurse and see how the South Bay clinic operated. At least three of the doctors who met with the nurse and then opened their own outpatient clinic each subsequently submitted claims to Medicare totaling more than $500,000 for serial, outpatient infusions of Natrecor. In a November 19, 2003 presentation to J&J officials, Scios officials acknowledged that Natrecor outpatient infusions were due in part to the Centers of Excellence program. In December 2003, Director of Sales Hillis included the Centers of Excellence program on a list of Scios's 2004 marketing programs for the outpatient market. Defendants' 2004 Business Plan for Natrecor called the Centers of Excellence program the primary tactic for achieving Scios's goal of doubling the number of outpatient clinics delivering more than 20 infusions of Natrecor per month. Defendants budgeted $750,000 for this program in 2004.

83. During the same year that Defendants budgeted $750,000 for the Centers of Excellence program in an effort to double the number of outpatient clinics delivering more than 20 infusions of Natrecor per month, Defendants provided the FDA with slides from an October 12, 2004 training presentation indicating that the sales force was being trained not to market Natrecor for scheduled infusions. The presentation, given by Scios's Senior Director, Health Care Compliance Director Naoko Fuji, stated that "we must not promote Natrecor for conditions requiring chronic, long-term or prophylactic therapy given that such promotion would not fall within the label indication currently approved for our drug."

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(4) Defendants' Ghostwriting

84. Beginning in 2003, Defendants hired a company called Ingenix to ghostwrite articles about Natrecor, including its outpatient use, and arranged to submit them for publication in journals. Ingenix wrote the articles and Defendants selected the doctors and nurses to place their names on the articles as "authors." The above-mentioned South Bay nurse and the cardiologist from the University of Texas Southwestern Medical Center, among many others, allowed Scios to use their names as "authors" of these ghostwritten articles. For example, Ingenix ghostwrote "Nesiritide in an Outpatient Infusion Clinic Setting - Experience in Treating 111 Patients for Up to 2 Years," ostensibly authored by the South Bay nurse and others; and "Potential Applications of Outpatient Nesiritide Infusions in Patients with Advanced Heart Failure and Concomitant Renal Insufficiency: Retrospective Results From the FUSION I Trial," ostensibly authored, *inter alia*, by the above-mentioned cardiologist.

(5) Defendants' Use Of CME To Promote Serial Outpatient Infusions

85. Rather than treating continuing medical education ("CME") as a non-promotional, educational endeavor, Scios included CME in its product marketing budget. For example, the 2002 budget included $900,000 for continuing medical education and $400,000 for continuing pharmacy education. Scios-sponsored CME included courses on outpatient infusions. For instance, in 2003, Scios sponsored a CME monograph entitled "Outpatient Management of Heart Failure: Program Development and Experience in Clinical Practice." The monograph included a Natrecor treatment algorithm. Copies of the monograph were provided to Defendants' sales force for distribution to health care professionals. In addition, Scios sponsored a web-based CME in 2003 entitled "Innovative Outpatient Treatment Options for the Decompensated Heart Failure Patient," whose speakers included the South Bay nurse and other health care professionals from outpatient clinics that used Natrecor. The sales force was provided with invitations to this course for distribution to customers. Scios had input into the content of CME through its ghostwriting company Ingenix and others. For example, Ingenix developed slide sets

for the Scios-funded INITIATE CME dinner programs and ghostwrote a CME monograph entitled "Strategies for Reducing Rehospitalization of HF Patients."

(6) ADHERE Registry

86. In 2001, Scios began a registry, called ADHERE, ostensibly to track treatment of CHF patients. In 2003, Scios created the ADHERE Longitudinal Module ("LM"), ostensibly "to gain a better understanding of patient outcomes and quality of care over time for patients with HF." ADHERE LM was directed at the outpatient population. One of Scios's true purposes in creating and sponsoring the ADHERE and ADHERE LM registries, however, was to utilize them as marketing tools. The registries provided Scios's sales force with a means of attracting the attention of doctors and nurses and starting a dialog about why they should use Natrecor. They also allowed Scios to gather and disseminate data it viewed as favorable regarding Natrecor, including outpatient Natrecor infusions. In addition, Scios held ADHERE meetings and ADHERE LM meetings at lavish hotels as a way to pay for doctors to take trips to desirable cities to attend presentations on the outpatient use of Natrecor. For example, the ADHERE LM kick-off meeting was held in May 2003 at the Ritz-Carlton in Washington, D.C. After these expensive meetings, Scios would assess its return on investment – the Natrecor sales generated as a result of the meetings.

87. Numerous documents authored by Defendants' employees refer to ADHERE's true purpose as a marketing tool. For example, at Scios's April 2002 National Sales Meeting, Associate Product Director Mark Rohman referred to ADHERE as the marketing program from which Scios would deliver the Natrecor message. In June 2002, Scios's Vice President of Medical Affairs, Darlene Horton, called a meeting with Scios Marketing and ADHERE management to discuss "the various marketing tactics related to the Registry." Scios Chief Executive Officer Richard Brewer's handwritten notes of his November 19, 2002 meeting with Scios Marketing Director George Mahaffey stated, *inter alia*, "Registry as a key to dominate this market."

88. A draft of the Natrecor 2003 Marketing Plan (reviewed by Brewer) stated that "[t]he ADHERE Registry is conducted to support the commercial operation." A draft of the Natrecor 2003 Business Plan (reviewed by Brewer) stated that "[t]he ultimate long-term goal of the ADHERE Registry includes supporting the key messages and demonstrating value of Natrecor treatment in several areas," and "[i]t is essential that the ADHERE database include large numbers of Natrecor patients to statistically prove positive effects." That document further stated that "[t]he ADHERE Registry is conducted to support the commercial operation. The registry must provide data, information and programs to increase effectiveness of the sales force and to further elevate the image of Scios in the heart failure community." A February 5, 2003 Scios document entitled "Promotional Tactics: Executive Summary" stated that "[s]ales data show a direct relationship between regional ADHERE meetings and regional sales gains."

89. J&J knew of, and approved, Scios's utilization of ADHERE for marketing purposes. For example, a presentation on Defendant's 2004 Natrecor Business Plan, given in July 2003 to J&J corporate officials by Scios's Vice President of Sales and Marketing Randy St. Laurent and Scios's Marketing Director George Mahaffey stated that "ADHERE is the foundation" for "2004 - year of extreme growth."

90. Similarly, Defendants' 2004 Natrecor Business Plan listed ADHERE LM and its meetings under "Outpatient Management Market - Business Driver - Number of Treaters." A February 5, 2003 Scios document entitled "Promotional Tactics: Executive Summary" stated that 18% of the promotional budget for outpatient infusion "has been ear-marked for the ADHERE LM kick-off meeting, advisory boards, and the Centers of Excellence Program." At Scios's April 2002 National Sales Meeting, Scios Marketing Director George Mahaffey referred to ADHERE LM as a phenomenal marketing tool. ADHERE LM was listed under "Outpatient Marketing Overview" in a presentation at Scios's July 19, 2002 Natrecor Outpatient Infusion Advisory Board meeting. At Scios's April 2004 National Sales Meeting, Clinical Registries Manager Patty Hynes discussed how ADHERE LM meetings led to an increase in Natrecor sales

for outpatient infusions.

(7) Reimbursement

91. Defendants knew that Medicare paid for the vast bulk of Natrecor used in the United States, including scheduled outpatient infusions. A presentation at the August 2001 Natrecor launch National Sales Meeting by Scios Vice President of Sales and Marketing Tom Feldman noted that "[o]ver 80% of the CHF patient population is over 65 years old." That same presentation noted that Medicare paid for 72.98% of the claims for CHF diagnosis code (ICD-9) 428.0, and stated that CHF is the "[s]ingle largest expense for Medicare." A presentation at Scios's July 19, 2002 Natrecor Outpatient Infusion Advisory Board meeting noted that reimbursement for outpatient infusions was from Medicare Part B. In a November 19, 2003 presentation to J&J officials, Scios officials stated that "CHF is [the] most significant Medicare healthcare cost burden." Defendants' January 31 to February 4, 2005 training for the Natrecor sales force stated that "Medicare is the primary payer for NATRECOR. Based on various claims analyses, we estimate that Medicare is the payer for 75% - 80% of NATRECOR used in the inpatient and outpatient settings."

92. Scios knew, even prior to the FDA's August 2001 approval of Natrecor, that Medicare reimbursement was key to physicians' decisions to use Natrecor in the outpatient setting.

93. Outpatient Reimbursement was listed under "Outpatient Marketing Overview" in a presentation at Scios's July 19, 2002 Natrecor Outpatient Infusion Advisory Board meeting. Defendants' March 2004 ADHERE Investigator Meeting likewise included a presentation on "Reimbursement Challenges and Opportunities in the Outpatient Management of Heart Failure."

94. Defendants established a reimbursement team, headed by Christopher Panarites, to handle reimbursement issues and the Medicare Contractors' local coverage determinations ("LCDs") regarding Natrecor. The main objective of Mr. Panarites's job was to maintain

unrestricted access to Natrecor in the outpatient setting.

95. Defendants contracted with a consultant, the Lash Group, to develop reimbursement guides that instructed health care professionals, in great detail, how to bill Medicare for outpatient infusions of Natrecor. While the guide provided limited information on billing for inpatient infusions, the vast majority of the guide, which was updated annually, covered billing in the hospital outpatient and physician office settings. The guide included, for example, detailed billing codes for the outpatient settings; instructions on how to complete claim forms and appeal denied claims; sample letters of medical necessity and appeals; and sample claim forms. The Defendants provided their Natrecor sales representatives with these reimbursement guides to distribute to Natrecor providers in the outpatient setting. The sales force also had laminated "Natrecor (nesiritide) Hospital Outpatient Reimbursement Quick Reference" and "Natrecor (nesiritide) Physician Office Reimbursement Quick Reference" handouts that showed health care professionals how to fill out a Medicare claim form for outpatient Natrecor infusions.

96. Defendants also provided a hotline number (staffed by the Lash Group) for health care professionals to call with Natrecor reimbursement questions. One of Scios's written sales aids from February 2002 instructed sales representatives to refer physicians to the reimbursement hotline if they needed assistance with outpatient reimbursement, noting that "[t]o imply or recommend reimbursement for off-label product uses (home health, intermittent usage) is considered Medicare Fraud and is punished severely."

97. At Scios's expense, the Lash Group also assisted providers through the Medicare appeal process for denied claims for payment.

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F. Increased Concerns About Natrecor

98. In the years after the drug's launch, concerns about the drug's safety increased. In early 2005, two articles were published in prominent medical journals relating to concerns of the renal and mortality effects of the drug.[1]

99. In response, Scios and J&J convened a panel of ten prominent cardiologists to review the safety and efficacy of Natrecor and issue recommendations about further clinical studies of the drug. Dr. Eugene Braunwald of Harvard Medical School and Brigham and Women's Hospital was the panel's Chairman, and it was known as "the Braunwald Panel." Scios provided the panel with its clinical data and requested that it issue recommendations regarding the use of Natrecor.

100. On June 13, 2005, the Braunwald Panel issued its report to Defendants. The Panel recommended that Scios should proceed with its current clinical trial program, including FUSION II, but also recommended that Scios conduct an additional trial to assess the effect of Natrecor on survivability because the evidence was insufficient and inconclusive regarding the long-term safety of Natrecor.

101. With respect to the outpatient use of Natrecor, the panel further recommended that the use of Natrecor be limited strictly to patients presenting to the hospital with acutely decompensated congestive heart failure who have dyspnea at rest (*i.e.,* the type of patients involved in the VMAC study). The panel further found that, because of the insufficiency of the evidence, Natrecor should not be used for, *inter alia*, intermittent outpatient infusions or scheduled repetitive use.

102. Upon receiving the Braunwald Panel's report, Scios's Senior Vice President of

[1] *See* Sackner-Bernstein JD, *et al.*, Short-term Risk of Death After Treatment With Nesiritide for Decompensated Heart Failure: A Pooled Analysis of Randomized Controlled Trials, 293 JAMA 1900 (2005); Sackner-Bernstein JD, *et al.*, Risk of Worsening Renal Function With Nesiritide in Patients With Acutely Decompensated Heart Failure, 111 Circulation 1487 (2005).

Medical Affairs, Darlene Horton, sent a Dear Healthcare Provider letter to healthcare providers (dated July 13, 2005) that admitted that FUSION I "was not powered to adequately assess the effectiveness or safety of serial infusions of Natrecor." And, despite Scios representing otherwise in its marketing of Natrecor, Dr. Horton further stated that "[t]he size of the study, its design, and its findings provide an inadequate basis to recommend the routine use of intermittent, serial, or scheduled repetitive infusions of Natrecor."

103. J&J orchestrated and controlled Scios's response to the Panel's criticism of Natrecor's use in the outpatient setting and recommendation, *inter alia*, that the drug be used strictly in the inpatient setting. For example, the day the Braunwald Panel issued its report to Scios, J&J executives prepared a response to the Braunwald Panel's recommendations.

104. On July 20, 2005, Dr. Braunwald sent a letter to Dr. Randall Kaye, Scios's Vice President of Medical Affairs, stating that "members of the Natrecor Advisory Panel have been disturbed by what we consider to be significant omissions and lack of clarity in Scios'[s] efforts to comply with the Panel's recommendations." On July 28, 2005, J&J Worldwide Chairman and Division Chairman of the Board, Joe Scodari, instituted a communications team comprised mostly of J&J employees to oversee the response to the Braunwald Panel's recommendations and all communications about Natrecor. Joe Scodari further ordered and participated in the team's weekly conference calls, and instructed Scios's President and CEO to "ensure a review on the *return* to promoting the on-label outpatient use (acute) is conducted" in Scios's 2006 Strategic Plan (emphasis added).

G. Noncoverage of the Off-Label Infusions by the Federal Health Care Programs

A. Medicare

105. During the period from 2002 through 2007, serial, scheduled outpatient infusions of Natrecor were not eligible for payment by Medicare because this off-label use was neither "reasonable and necessary," nor "medically accepted." The off-label use was not supported by any major drug compendia, authoritative medical literature, and/or accepted

standards of practice. Indeed, the use was not supported by *any* credible study showing that the serial outpatient infusions were effective.

106. In 2004 and 2005, Scios, without any scientific support for the efficacy of the serial infusions, urged Medicare Contractors to cover serial outpatient infusions. For example, Scios routinely touted both the safety and alleged efficacy results of the limited FUSION I study to the Medicare Contractors in an effort to support coverage. Five Medicare Contractors (three in the New York region) issued Local Coverage Determinations ("LCDs") allowing limited coverage for the outpatient serial use of Natrecor; two of these Medicare Contractors (outside of the New York region) reversed the LCDs after the issuance of the Braunwald Panel report. A number of other Medicare Contractors specifically denied coverage for this use.

107. On May 17, 2005, a group of Medicare Contractors' Directors, including two who allowed the limited coverage, submitted a formal request to CMS for a National Coverage Determination ("NCD") on Natrecor, noting that "the specific reason for our NCD request focuses on the 'off-label' use of intravenous Nesiritide," *i.e.,* "intravenous Nesiritide in chronic CHF and maintenance therapy." The request further noted that despite the fact FUSION I did not evaluate the clinical efficacy and long-term outcomes of Natrecor in the chronic CHF population, "the results of the FUSION I Trial have been extrapolated to expand the utilization of Nesiritide to chronic CHF and maintenance therapy in the outpatient setting."

108. In response to this NCD request, CMS conducted an exhaustive review of the available research allegedly supporting the outpatient use of Natrecor for CHF and subsequently issued an NCD in March 2006, denying Medicare coverage for this off-label use. In the NCD, CMS explained:

> Much of the reported research on the use of nesiritide for the intermittent treatment of chronic heart failure appears in abstracts and has not yet been published as full peer-reviewed journal articles. In general, abstracts do not provide sufficient information for us to evaluate the strength of the reported findings critically. As such, these abstracts do not constitute strong evidence and are given less weight than other evidence. The published articles [including the article published on FUSION I] supporting the off-label use of nesiritide for chronic heart failure are

> hampered by methodological shortcomings, including small sample size and the lack of long term outcome data.

109. CMS concluded that "[t]hese weaknesses, along with the incidence of renal dysfunction, the increased incidence of mortality, and the findings and recommendations of the Nesiritide Advisory Panel create substantial concerns about the net health outcomes associated with the use of this drug for chronic heart failure. . . .CMS has determined that there is sufficient evidence to conclude that the use of nesiritide for the treatment of chronic heart failure is not reasonable and necessary for Medicare beneficiaries in any setting."

110. Thus, CMS confirmed that the serial, scheduled off-label infusions of Natrecor do not meet the coverage requirements of Medicare.

B. TRICARE and FEHBP

111. During the periods from 2002 through 2007, serial, scheduled Natrecor infusions also were not eligible for payment by TRICARE or FEHBP.

112. TRICARE did not cover this off-label use because the use was not proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies.

113. The FEHBP did not cover this off-label use because the use was not medically necessary.

VII. FALSE CLAIMS

A. Medicare

114. During the period from 2002 through 2007, Defendants, through their unlawful conduct discussed in Paragraphs 1 through 113 above, caused over 4,000 health care providers to submit over 157,641 claims to Medicare for serial, outpatient Natrecor infusions and ancillary services. The claims are false because the off-label use is not covered.

115. In order to protect patient confidentiality, rather than listing the false claims in this Complaint, the United States has provided Defendants with a database listing each false

claim for serial, outpatient infusions and ancillary services they caused to be submitted during the period from 2002 through 2007.

116. By way of example, Defendants caused the following health care providers to submit claims to Medicare for non-covered serial, outpatient infusions of Natrecor for which Medicare paid the following total amounts:

South Bay Cardiovascular Associates	$3,101,745
Desert Valley Medical Group	$1,680,317
Heart Center of Sarasota	$1,527,159
Amityville Heart Center	$1,447,691
Louisiana Heart Center	$1,162,866
The Heart Institute of Brownsville	$1,159,214
Coast Cardiology Center	$1,114,592
Harbor Medical Associates	$1,077,776

117. One or more of the doctors and nurses at each of these health care providers were affiliated with Defendants in that they were paid speakers or recipients of grant funds from Defendants; participated in the ADHERE LM registry, the Centers of Excellence program, or the FUSION II study; attended Scios-sponsored marketing programs such as ADHERE and ADHERE LM meetings, CME seminars, and other meetings discussing the serial, outpatient use of Natrecor; and/or started using Natrecor in the outpatient setting after receiving information from Scios's sales force about the serial, outpatient use of Natrecor, how to set up an outpatient clinic for such use, or how to obtain Medicare reimbursement for such use.

118. For instance, South Bay Cardiovascular Associates, Desert Valley Medical Group, Louisiana Heart Center, The Heart Institute of Brownsville, and Harbor Medical Associates all participated in Defendants' ADHERE LM registry and/or employed a doctor or nurse who attended one or more ADHERE LM meetings. South Bay Cardiovascular Associates, Desert Valley Medical Group, Heart Center of Sarasota, and Coast Cardiology Center all

employed a doctor or nurse whom Defendants paid to speak about Natrecor. For example, as explained above, Defendants paid the South Bay nurse over $100,000 for the promotional speeches and training she provided on the outpatient use of Natrecor. This nurse in turn "share[d] her data and experience in the OP market" with "target audiences" that included the doctor and nurse at the Heart Center of Sarasota and numerous other health care providers. In 2004, Defendants praised the sales representative responsible for marketing Natrecor to Amityville Heart Center for becoming a "true consultant" and "true business partner" with a doctor at this outpatient clinic.

B. Damages to Other Federal Programs

(1) TRICARE

119. During the period from 2002 through 2007, Defendants, through their unlawful conduct discussed in Paragraphs 1 through 113 above, caused health care providers to submit over 9,581 claims to TRICARE for serial, outpatient Natrecor infusions and ancillary services. These claims are false because they were not covered. In order to protect patient confidentiality, rather than listing the false claims in this Complaint, the United States has provided Defendants with a spreadsheet listing each false claim for serial, outpatient infusions they caused to be submitted to TRICARE during the period from 2002 through 2007.

(2) FEHBP

120. During the period from 2002 through 2007, Defendants, through their unlawful conduct discussed in Paragraphs 1 through 113 above, caused health care providers to submit over 3,692 claims to FEHBP for serial, outpatient Natrecor infusions and ancillary services. At least 2,172 claims were submitted to Blue Cross and Blue Shield; at least 512 claims were submitted to Government Employees Hospital Association, Inc.; and at least 1,008 false claims were submitted to the Mail Handlers Benefit Plan. These claims are false because they were not covered. In order to protect patient confidentiality, rather than listing the false claims in this Complaint, the United States has provided Defendants with a spreadsheet listing each false claim

for serial, outpatient infusions they caused to be submitted to FEHBP during the period from 2002 through 2007.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)

(31 U.S.C. § 3729(a)(1) (2008))

121. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

122. Scios and J&J knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the scheduled, serial use of Natrecor that were not covered by the federal health care programs.

123. By virtue of the false or fraudulent claims that Scios and J&J caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

SECOND CAUSE OF ACTION

(Unjust Enrichment)

124. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

125. As a consequence of the acts set forth above, Scios and J&J were unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

126. The United States claims the recovery of all monies by which Scios and J&J have been unjustly enriched.

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PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Scios and J&J as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the amounts by which Scios and J&J were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States demands a jury trial in this case.

Respectfully submitted,

TONY WEST
Assistant Attorney General

JOSEPH P. RUSSONIELLO
United States Attorney

Dated: June 11, 2009 By: _/s/_____
SARA WINSLOW
JULIE A. ARBUCKLE
Assistant United States Attorneys

Dated: June 11, 2009 By: _/s/_____
JOYCE R. BRANDA
PATRICIA R. DAVIS
RENÉE S. ORLEANS
Civil Division, U.S. Department of Justice

Attorneys for the United States